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10/749,640

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Lawrence M. Boyd

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03/07/2008

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EXAMINER

HARVEY, JULIANNA NANCY

ART UNIT

PAPER NUMBER

4153

MAIL DATE

DELIVERY MODE

03/07/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                       |                                    |  |
|------------------------------|---------------------------------------|------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/749,640  | <b>Applicant(s)</b><br>BOYD ET AL. |  |
|                              | <b>Examiner</b><br>Julianna N. Harvey | <b>Art Unit</b><br>4153            |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 36-38 and 41-51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 36-38 and 41-51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 June 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date. _____.                                     |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)                                      | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8 Mar. 2004, 24 May 2004, 14 June 2004, 31 Aug. 2004, 6 Feb. 2006, 13 Mar. 2006, 6, Feb. 2008.</u> | 6) <input type="checkbox"/> Other: _____.                         |



## DETAILED ACTION

### *Note to Applicant*

This application contains two original claims numbered 38, one of which is dependent on claim 37 and one of which is an independent claim. For purposes of this Office Action, the claim 38 that is dependent on claim 37 (and non-elected with traverse in the reply filed on January 22, 2008) will be referred to as claim 38A. The claim 38 that is independent (and non-elected without traverse) will be referred to as 38B.

### *Election/Restriction*

The requirement for restriction mailed on January 8, 2008 has been withdrawn in part. In light of applicant's election of claims 41-43 and applicant's argument that the subject matter of claim 36 overlaps that of claim 41, the examiner has reconsidered and withdrew the election requirement as between claims 36-38A and claims 41-43.

Applicant's election **without** traverse of methods for spinal fixation (claims 36-43) in the reply filed on January 22, 2008 is acknowledged. Claims 1-35 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Claims 38B-40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Furthermore, applicant has indicated that claims 1-35 and 38B-40 are cancelled without prejudice.

### ***Information Disclosure Statement***

Two entries on the IDS filed on March 8, 2004 have not been considered. On page 2 of 9, the entry identified as "BS", which corresponds to "Various Abstracts of Articles on the "X-Stop" Interspinous Spacer, Various Authors, date unknown", has not been considered because it has not been properly identified. If applicant would like this entry considered, the examiner suggests submitting a new 1449 form with each abstract identified by author and title. On page 4 of 9, the entry identified as "DH", which corresponds to document number US 6,514,225 and author Ferrce, has not been considered because US 6,514,225 belongs to Utterberg, not Ferrce.

### ***Claim Objections***

Claim 36 is objected to because of the following informalities: "bone anchor coupled" in line 7 should be "bone anchors coupled." Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 37 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites the limitation "all or part of the intervertebral disc between at least two motion segments." However, if there are at least two motion segments, there are at least two discs. Thus, the examiner is unsure of whether

applicant means disc in the singular form (i.e., "an intervertebral disc") or the plural form (i.e., "the intervertebral discs"). Furthermore, the specification sheds no light on the issue as the only mention of replacing at least a disc between motion segments is made on page 7, lines 18-19 using the same language as the claim. As such, the examiner has interpreted the claim as broadly as is reasonable such that the limitation reads "all or part of an intervertebral disc between at least two motion segments."

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dixon et al. (US 2001/0037111 A1) in view of Muckter (US 2002/0198527 A1). Dixon et al. teach a method for dynamic stabilization of motion segments of the spine comprising the steps of: positioning a stabilization element adjacent the spine (see page 3, paragraph 62), the stabilization element configured to span a length of the spine between at least two motion segments (see figure 13); engaging bone anchors to at least two motion segments (see pages 3-4, paragraph 63); and coupling the bone anchors to the stabilization element (see pages 3-4, paragraph 63 and page 4, paragraph 65). Dixon et al. fail to teach that at least one of the bone anchors is coupled to permit deflection of the bone anchor between the stabilization element and the motion segment. Muckter

teaches a bone anchor that is capable of deflection between the head and the threaded portion (see shaft "16" in figure 5 in conjunction with page 3, paragraph 44). It would have been obvious to one of ordinary skill in the art at the time the invention was made to replace the bone screws used by Dixon et al. with those suggested by Muckter as doing so would eliminate the need to use a spacer to achieve dynamic stabilization, thereby simplifying the surgical procedure.

Claim 37 and 38A are rejected under 35 U.S.C. 103(a) as being unpatentable over Dixon et al. (US 2001/0037111 A1) in view of Muckter (US 2002/0198527 A1) as applied to claim 36 above, and further in view of Serhan et al. (US 2002/0143329 A1), Bao et al. (US 5,534,028), and Martin (US 6,132,464). The Dixon et al. in view of Muckter modifications as indicated in claim 36 above fail to teach that the method further comprises the step of repairing or replacing all or part of the intervertebral disc between at least two motion segments (claim 37) and that the step of repairing or replacing includes replacing all or part of the nucleus pulposus with a polymeric prosthesis having physical properties substantially similar to the physical properties of a natural nucleus pulposus (claim 38). Serhan et al. teach a rigid spinal stabilization system that includes the step of replacing the intervertebral disc with fusion devices (see page 10, paragraph 186). Bao et al. teach a prosthetic nucleus pulposus made of hydrogel, a polymer, that has physical properties that are substantially similar to the physical properties of a natural nucleus pulposus (see column 3, lines 13-24). Martin teaches that in some cases, it is necessary to replace the intervertebral disc without sacrificing mobility of the spine (see column 9, lines 54-59). It would have been obvious

to one of ordinary skill in the art at the time the invention was made to further modify the Dixon/Muckter method such that it includes replacing part of the intervertebral disc, as suggested by Serhan et al., with a hydrogel prosthetic nucleus pulposus, as suggested by Bao et al., as in some cases it may be necessary to replace the disc without sacrificing mobility.

Claims 41-44, 46, and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dixon et al. (US 2001/0037111 A1) in view of Muckter (US 2002/0198527 A1), Serhan et al. (US 2002/0143329 A1), Bao et al. (US 5,534,028), and Martin (US 6,132,464). Dixon teaches a method for dynamic stabilization of a motion segment of the spine comprising the step of: coupling a dynamic stabilization system across at least two motion segments (see page 3, paragraph 62; pages 3-4, paragraph 63; and page 4, paragraph 65) using at least two bone anchors with head portions configured for engagement to a stabilization element outside the vertebral body (see page 3, paragraph 46) and engagement portions configured for engagement within the motion segment (see page 3, paragraph 44). Dixon fails to teach that the method includes introducing a device into an intervertebral space to at least partially maintain or restore the natural motion of the disc at the motion segment (claim 41); that the system includes at least one bone anchor that permits natural motion of the disc by deforming a portion of the bone anchor (claim 41); that the device includes a device for replacing or augmenting the nucleus pulposus of the intervertebral disc (claim 42); that the step of introducing a device includes introducing a polymeric prosthesis to replace or augment the nucleus pulposus in which the polymeric prosthesis exhibits physical properties



similar to the natural nucleus pulposus (claim 43); that the polymeric prosthesis is formed of a hydrogel (claim 44); that the bone anchor includes a flexible portion between the engagement portion and the head portion (claim 46); and at least one anchor includes a flexible portion between the head portion and the engagement portion configured to permit relative movement between the head portion and the engagement portion (claim 47). Muckter teaches a bone anchor that has a flexible portion (see shaft "16" in figure 5) located between the head portion and the engagement portion such that it is capable of deformation (see page 3, paragraph 44). Serhan et al. teach a rigid spinal stabilization system that includes the step of replacing the intervertebral disc with fusion devices (see page 10, paragraph 186). Bao et al. teach a prosthetic nucleus pulposus made of hydrogel, a polymer, that has physical properties that are substantially similar to the physical properties of a natural nucleus pulposus (see column 3, lines 13-24). Martin teaches that in some cases, it is necessary to replace the intervertebral disc without sacrificing mobility of the spine (see column 9, lines 54-59). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Dixon et al. method such that the bone screws used by Dixon et al. were replaced by those suggested by Muckter as doing so would eliminate the need to use a spacer to achieve dynamic stabilization, thereby simplifying the surgical procedure. It would have been obvious to further modify the Dixon et al. method such that it includes introducing a device into an intervertebral space, as suggested by Serhan et al., such that the device is a hydrogel prosthetic nucleus

pulposus, as suggested by Bao et al., as in some cases it may be necessary to replace the disc without sacrificing mobility.

Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dixon et al. (US 2001/0037111 A1) in view of Muckter (US 2002/0198527 A1), Serhan et al. (US 2002/0143329 A1), Bao et al. (US 5,534,028), and Martin (US 6,132,464) as applied to claim 42 above, and further in view of Fleischmann et al. (US 6,375,682 B1). The Dixon et al. in view of Muckter, Serhan et al., Bao et al., and Martin modifications as indicated in claim 42 above fail to teach that the device for replacing or augmenting the nucleus pulposus is a mechanical device. Fleischmann et al. teach a mechanical device for replacing the nucleus pulposus (see column 6, lines 43-52). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Dixon/Muckter/Serhan/Bao/Martin combination such that the Fleischmann et al. mechanical device was used to replace the nucleus pulposus as such a device can be adjusted to fit the individual patient and would also allow post-operative adjustments (see column 3, lines 19-25 of Fleischmann et al.).

Claims 48-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dixon et al. (US 2001/0037111 A1) in view of Serhan et al. (US 2002/0143329 A1), Bao et al. (US 5,534,028), and Martin (US 6,132,464). Dixon et al. teaches a method for dynamic stabilization of a motion segment of the spine comprising the step of: coupling a dynamic stabilization system across the motion segment (see page 3, paragraph 62; pages 3-4, paragraph 63; and page 4, paragraph 65). Dixon et al. fail to teach that the method includes introducing a device into an intervertebral space to at least partially

maintain or restore the natural motion of the disc at the motion segment (claim 48); that the device includes a device for replacing or augmenting the nucleus pulposus of the intervertebral disc (claim 49); that the step of introducing a device includes introducing a polymeric prosthesis to replace or augment the nucleus pulposus in which the polymeric prosthesis exhibits physical properties similar to the natural nucleus pulposus (claim 50); and that the polymeric prosthesis is formed of a hydrogel (claim 51). Serhan et al. teach a rigid spinal stabilization system that includes the step of replacing the intervertebral disc with fusion devices (see page 10, paragraph 186). Bao et al. teach a prosthetic nucleus pulposus made of hydrogel, a polymer, that has physical properties that are substantially similar to the physical properties of a natural nucleus pulposus (see column 3, lines 13-24). Martin teaches that in some cases, it is necessary to replace the intervertebral disc without sacrificing mobility of the spine (see column 9, lines 54-59). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Dixon et al. method such that it includes introducing a device into an intervertebral space, as suggested by Serhan et al., such that the device is a hydrogel prosthetic nucleus pulposus, as suggested by Bao et al., as in some cases it may be necessary to replace the disc without sacrificing mobility.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julianna N. Harvey whose telephone number is 571-

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270-3815. The examiner can normally be reached on Mon. - Fri., 7:00 a.m. - 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jackson can be reached on 571-272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J.N.H./

Examiner, Art Unit 4153

27 February 2008

/Gary Jackson/

Supervisory Patent Examiner

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